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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/644,576 | 08/20/2003 | Connie Sanchez | 05432/100M919-US5 | 5194 |

7278 7590 01/02/2008

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| EXAMINER | |
|---|---|
| CHONG, YONG SOO | |
| **ART UNIT** | **PAPER NUMBER** |
| 1617 | |

| MAIL DATE | DELIVERY MODE |
|---|---|
| 01/02/2008 | PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/644,576 | SANCHEZ ET AL. | |
| | Examiner | Art Unit | |
| | Yong S. Chong | 1617 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *31 October 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *20-37* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *20-37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/12/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Status of the Application*

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/31/2007 has been entered.

Claim(s) 1-19 have been cancelled. Claim(s) 20-37 are pending and examined herein.

Applicant's arguments have been fully considered but found not persuasive. The rejection of the last Office Action is maintained for reasons of record and modified below.

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in Graham vs John Deere Co., 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 20-37 are rejected under 35 U.S.C. 103(a) as being obvious over Audia et al. (US Patent 5,846,982) in view of Boegesoe et al. (US Patent 4,943,590) and Shaller et al. (J. Neuropsychiatry and Clinical Neurosciences, 11:4, Fall 1999, abstract).

The instant claims are directed to a method of treating attention deficit hyperactivity disorder (ADHD) by administering escitalopram.

Audia et al. teach that attention deficit hyperactivity disorder (col. 53, line 7) can be treated with compounds that inhibit serotonin reuptake (abstract).

However, Audia et al. fail to specifically disclose escitalopram.

Boegesoe et al. teach the method of treating depression in a patient with the (+) enantiomeric form of citalopram, otherwise referred to as escitalopram, by inhibiting the uptake of serotonin (col. 1, lines 9-26). Acceptable pharmaceutical salts of escitalopram include oxalate (col. 1, lines 29-42) and also its crystalline form (example 2). What's more, daily dosage of escitalopram is disclosed to be from 5 to 50 mg (col. 8, lines 55-60).

Moreover, Shaller et al. teach that attention deficit hyperactivity disorder increases one's risk for both major depression and an anxiety disorder by approximately 25%.

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed invention was made, to administer patients suffering from attention deficit hyperactivity disorder an effective amount of the specific serotonin reuptake inhibitor, escitalopram.

A person of ordinary skill in the art would have been motivated to administer patients suffering from attention deficit hyperactivity disorder an effective amount of the specific serotonin reuptake inhibitor, escitalopram, because: (1) Audia and Boegesoe et al. are analogous art since both teach treating disorders by inhibiting serotonin reuptake; (2) Audia et al. teach specifically treating attention deficit hyperactivity disorder with a serotonin reuptake inhibitor; (3) Boegesoe et al. teach specifically that escitalopram is a serotonin reuptake inhibitor; (4) the functional equivalence of escitalopram and another serotonin reuptake inhibitor; (5) Boegesoe et al. also teach the treatment of depression with a serotonin reuptake inhibitor; (5) treating a patient suffering from depression with escitalopram will also treat the same patient who is suffering from attention deficit hyperactivity disorder; and (6) Shaller et al. discloses that the risk of depression is increased in attention deficit disorder patients, the motivation to administer escitalopram to ADHD patients is because of the reasonable expectancy of decreasing the risk of depression. Therefore, one of ordinary skill in the art would have had a reasonable expectation of success in treating attention deficit hyperactivity disorder in a patient by administering an effective amount of the serotonin reuptake inhibitor, escitalopram.

***Response to Arguments***

Applicant argues that the administration of sertraline, an SSRI, had absolutely no effect on the patient's ADHD in Schaller since "the patient still met the criteria for adult ADHD." Therefore, a person of ordinary skill in the art reading Shaller would have not predicted that sertraline, or another other SSRI, would effectively treat ADHD as the one SSRI administered in Schaller failed to treat the patient's ADHD.

This is found not persuasive because Applicant cannot make such definitive conclusions based on a single case report of a 38-year-old man with depression. At the outset, the Schaller reference was only used to show that ADHD increases one's risk for major depression. Applicant's arguments directed toward sertraline have nothing to do with the obviousness rejection since sertraline was not claimed. Examiner notes that instant claims and the 103(a) obviousness rejection both recite the particular SSRI, escitalopram, which is not mentioned anywhere in the Schaller reference. Furthermore, there is no mention in the Schaller reference that SSRIs are not effective in treating ADHD or depression. Applicant has misinterpreted the cited prior art references by making sweeping statements about all SSRIs based on a single SSRI, which is not even mentioned in the instant claims or the rejection. Examiner reminds Applicant that the standard for obviousness is not absolute, but rather a reasonable expectation of success.

Applicant continues to argue that Audia does not disclose or suggest that any serotonin reuptake inhibitor can be used to treat ADHD, rather only tetrahydropyridinyl-

and piperidinyl-indoles and benzothiophenes are useful in treating ADHD, in which classes escitalopram does not fall into.

This is not persuasive because Audia was used to make the general statement that ADHD can be treated with compounds that inhibit serotonin reuptake. The specific serotonin reuptake inhibitor, escitalopram, is disclosed in the secondary reference, Boegesoe et al.

In response to applicant's arguments against the references, one cannot show nonobviousness by attacking references individually where the rejections are based on the combination of references. See *In re Keller*, 642 F. 2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F. 2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

### *Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong S. Chong whose telephone number is (571)-272-8513. The examiner can normally be reached on M-F, 9-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, SREENI PADMANABHAN can be reached on (571)-272-0629. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

YSC